Breakout Sessions BLOCK #1 – 2:00PM

These sessions will focus on education and training for industry and regulators, identifying potential partners for outreach and implementation, and technical assistance.

Session Topic: Preventive Controls (*This session will be webcast.)*
Grand Ballroom A/B

Facilitators:
Dianne Milazzo, *Consumer Safety Officer, Office of Surveillance and Compliance, Division of Compliance, Post Market Compliance Team, Center for Veterinary Medicine, FDA*
***Deb DeVlieger**, National Food Expert, Office of Food and Feed, Office of Regulatory Affairs, FDA*

Questions:

- What types of technical assistance and outreach will industry most likely need?
  - For human food facilities?
  - For animal food facilities?
- How can FDA best provide useful technical assistance and outreach?
  - Is there particular information FDA should provide?
  - Are there different ways to provide technical assistance depending upon size, location, type of food (human or animal) that we should be aware of?
- What kinds of guidance documents, or other technical assistance and outreach tools would be most helpful in developing a Food Safety Plan?

Session Topic: Produce
Grand Ballroom C/D

Facilitators:
Kevin Gerrity, *Consumer Safety Officer / National Food Expert, Office of Food and Feed Operations, Division of Food and Feed Operations and Inspections, Office of Regulatory Affairs, FDA*
Jennifer Thomas, *Acting Director, Compliance Policy Staff, Office of Compliance, Center for Food Safety and Applied Nutrition, FDA*

Questions:

- What are the best ways to conduct outreach and provide educational information to the farming community?
- There are different forms of technical assistance, such as guidance documents, webinar presentations, toolkits, and on-site technical assistance. Given the diversity in the farming community, what forms of technical assistance would be most beneficial short term vs long term, and which would you recommend FDA provide or play a role in providing?
- What educational information/topics would be most useful to the farming community?

Session Topic: Imports - Foreign Supplier Verification Program
Grand Ballroom E

Facilitator:
Sharon Lindan Mayl, *Senior Advisor for Policy, Office of Foods and Veterinary Medicine, FDA*

Questions:

- What type of technical assistance and outreach will the import community most likely need, and which FDA could best provide?
- What kinds of guidance documents, or other technical assistance and outreach tools, would be most helpful in meeting the FSVP rule requirements?
- How do we reach importers who will be subject to the FSVP rule and are not currently regulated by FDA, in order to increase their awareness of pending regulations and final requirements?
    - Are there particular networks for this community that can facilitate outreach?
- What other stakeholders, besides importers, should we target for outreach and why?
- What are your biggest challenges to compliance with the FSVP rule and associated requirements?
- What role do you believe importers should play in educating their suppliers to comply with FSMA requirements?

Session Topic: Intentional Adulteration
Junior Ballroom 3

Facilitators:
Marion Allen, *Senior Food Defense Outreach and Education Coordinator, Food Defense and Emergency Coordination Staff, Office of Analytics and Outreach, Center for Food Safety and Applied Nutrition, FDA*
Ryan Newkirk, *Policy Analyst, Food Defense and Emergency Coordination Staff, Office of Analytics and Outreach, Center for Food Safety and Applied Nutrition, FDA*

Questions:
FDA is aware that intentional adulteration (IA)/food defense is a new component of human foods inspections and therefore a significant amount of industry and regulator training will be required in this area. FDA is considering an educational approach to training in the first few years of implementation, focusing on the following areas: (1) industry and regulator readiness, (2) education for regulated industry and regulators in order to facilitate consistency in IA/food defense approaches/plans, (3) adequacy of corporate-wide programs (e.g. food defense plan development), and (4) establishing standardized training curriculum for industry and regulators.

- What are your views of pros and cons of this approach?
- What are your views on the formation of a specially trained dedicated cadre of personnel? What should the cadre's role be – inspecting for adequacy and/or facilitating implementation?
- In your opinion, would this type of approach improve compliance and public health outcomes? Why or why not?

FDA is considering forming a dedicated external Food Defense Training Alliance for Human Foods or participating in an existing alliance under the Food Safety Preventive Controls Alliance (FSPCA). The food defense experts under the alliance would provide technical assistance and outreach to small/very small businesses to enhance food defense awareness and compliance, when appropriate, with the Intentional Adulteration rule for human foods.

- What are your views of the pros and cons based on this approach?
- In your opinion, would this type of approach improve compliance and public health outcomes? Why or why not?

Breakout Sessions BLOCK #2 – 3:15PM

These sessions will focus on data needs, inspection approaches/changes, and compliance and enforcement considerations related to each operational aspect of FSMA implementation.

Session Topic: Produce (*This session will be webcast.)*
Grand Ballroom A/B

Facilitator:
Ingrid Zambrana, *District Director, Atlanta District Office, Office of Regulatory Affairs, FDA*
Fazila Shakir, *Consumer Safety Officer, Division of Produce Safety, Office of Food Safety, Center for Food Safety and Applied Nutrition, FDA*

Questions:

- What should regulators take into consideration when developing an inspection program? For example, should regulators consider farming schedule (peak/non-peak), inspection frequency, etc.?
- What are the farming community's recommendations for inspections in terms of what should happen before, during, and after an inspection?
- What information would farmers find useful in advance of, during, and/or at the conclusion of an inspection?
- What incentives might FDA provide or establish to encourage farms to come into compliance with the Produce Safety rule?
- Would a pre-assessment be of interest to the farming community?
    - Why or why not?
    - What do you recommend regulators take into consideration when designing a pre-assessment program to support moving the farming community towards compliance with the produce safety rule?

Session Topic: Preventive Controls
Grand Ballroom C/D

Facilitators:
Priya Rathnam, *Supervisory Consumer Safety Officer, Division of Enforcement, Office of Compliance, Center for Food Safety and Applied Nutrition, FDA*
Scott J. MacIntire, *Director, Division of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs, FDA*

Questions:

- What do you see as the biggest challenges to inspection and compliance under the PC rule for your industry?
- What do you think FDA should do, or help do, to resolve those challenges?
- What incentives would you like to see FDA implement to recognize and/or encourage compliance with the PC regulations?
- What characteristics do you envision define a successful inspection approach?
- What makes a successful compliance strategy?

Session Topic: Imports – Third- Party Auditor Program
Grand Ballroom E

Facilitator:
Charlotte Christin, *Special Assistant to the Director of the Office of Compliance, Center for Food Safety and Applied Nutrition, FDA*

Questions:

- How do we help increase awareness of the third-party auditor program among *accreditation bodies** and *food safety certification bodies*** across the globe?
    - Are there initiatives underway we can help support or tap into in order to provide information or leverage?
- What is the best means to share information with foreign food facilities about the third-party auditor program (e.g., those who aren't subject to the new FSMA regulations but who may want to seek certification under FDA's third-party auditor program to sell their food to importers participating in the Voluntary Qualified Importer Program)?
- Are there particular operational challenges for FDA in overseeing a program with both public and private accreditation bodies and certification bodies? What solutions could be considered in addressing those challenges?

** Accreditation body refers to an authority that performs accreditation of third-party auditors.*
*** Food safety certification body or third-party auditor refers to a foreign government, agency of a foreign government, foreign cooperative, or any other appropriate third party that is eligible to be considered for accreditation to conduct food safety audits to certify that eligible entities meet the applicable FSMA requirements.*

Session Topic: Intentional Adulteration
Junior Ballroom 3

Facilitators:
Marion Allen, *Senior Food Defense Outreach and Education Coordinator, Food Defense and Emergency Coordination Staff, Office of Analytics and Outreach, Center for Food Safety and Applied Nutrition, FDA*
Ryan Newkirk, *Policy Analyst, Food Defense and Emergency Coordination Staff, Office of Analytics and Outreach, Center for Food Safety and Applied Nutrition, FDA*

Questions:
FDA is aware that intentional adulteration (IA) may be new to many firms/facilities that will be covered by the rule. We are considering as an option that the first few years of implementation will consist of: (1) inspectional data acquisition (possibly checking for presence/absence of data during a preventive controls inspection), (2) education to facilitate consistency in IA/food defense approaches/plans by the regulated industry, and (3) identification of areas/components specific to the IA rule that may require additional assistance/guidance for compliance (e.g., identification of actionable process steps, identification/implementation of focused mitigation strategies, monitoring of mitigation strategies, corrective actions for strategies, and verification activities). This would allow us to build up information related to IA compliance, and potentially focus IA inspections on a subset of regulated facilities based on risk.

- What are your views of pros and cons based on this approach?
- In your opinion, would this type of approach improve compliance and public health outcomes? Why or why not?

FDA is considering, as an option, an inspection approach for firms with corporate oversight that involves tiered inspections conducted by regulator staff with the correct level of expertise and training. The thought is that we could determine the adequacy of the food defense plan (at the corporate level)

before assessing implementation at a corporate lead facility, and that this may assist in industry compliance.

- What are your views of the pros and cons based on this approach?
- What are your views on the formation of a specially trained dedicated cadre of personnel? What should the cadre's role be – inspecting for adequacy and/or facilitating implementation?
- One of the concerns noted to FDA is access to/copying of food defense plans – does this approach assist with this issue or not? If not, are there alternative approaches that may be useful in this discussion?
- In your opinion, would this type of approach improve compliance and public health outcome? Why or why not?

Breakout Sessions BLOCK #3 – 4:30PM

These sessions will cover common themes that expand across the various operational aspects of FSMA implementation.

Session Topic: Leveraging and Collaborating Private Partners across the Globe (This session will be webcast.)
Grand Ballroom A/B

Facilitator:
Charlotte Christin, *Special Assistant to the Director of the Office of Compliance, Center for Food Safety and Applied Nutrition, FDA*

Questions:

- What are the key challenges and/or concerns with FDA leveraging/collaborating with international private partners, and how can they be addressed effectively?
- How do you envision FDA collaborating with private partners internationally?
- Are there models for global public-private collaborations on regulatory implementation you think we should review/consider and why?
- What types of (or areas of) leveraging and collaborations would be most helpful to our private partners across the globe?
- What are the best means of identifying and reaching out to international private partners who might be interested in leveraging or collaborating with FDA on FSMA implementation?

Session Topic: Performance Metrics
Grand Ballroom C/D

Facilitator:
Sherri McGarry, *Senior Advisor, Resource Planning and Strategic Management, Office of Foods and Veterinary Medicine, FDA*

Questions:

- What are the top 3 results in the FSMA teams' strategic frameworks* that are most important to monitor/measure, in order to demonstrate successful FSMA implementation, and why?
- What are some of the most efficient ways to obtain stakeholder data and their views as FDA selects metrics and assesses our ability to monitor progress, from a data-driven standpoint, in implementing FSMA?
- What are the best approaches for measuring increased knowledge of the rules by a) industry, b) government food and feed safety staff who conduct or support inspections and compliance activities?
- How should FDA report out to stakeholders on the progress in implementing FSMA once we begin monitoring performance? How do we find out from stakeholders their view on how well we're making progress?
- Many strategic objectives and high level results are similar across the FSMA teams' frameworks and focus on reducing the risk of illness or injury with foods subject to the FSMA rules. Are there approaches we should consider for measuring a reduction in foodborne illness or injury to FSMA implementation?

* There will be a brief overview of the cross-cutting results in the FSMA teams' strategic frameworks.

Session Topic: FSMA's New Import System
Grand Ballroom E

Facilitator:
Doriliz De Leon, *Consumer Safety Officer, Division of Enforcement/Office of Compliance, Center for Food Safety and Applied Nutrition, FDA*

Questions:

- How does the import system FSMA envisions align with current import practices?
- Do you have concerns about how FDA's new import system will align with the U.S. Customs and Border Protection's current border activities related to food importation? How should they align, why and how best can this alignment be accomplished?
- What are your biggest challenges as we move toward the preventive-oriented system for imports envisioned in FSMA? How can FDA or others help address the challenges?
- What are your biggest opportunities relative to the new import system? How can FDA or others help build on those opportunities?
- How will we know if we have achieved success? What should we measure?

Session Topic: Establishing Research Priorities
Junior Ballroom 3

Facilitator:
Samir Assar, *Director, Division of Produce Safety, Center for Food Safety and Applied Nutrition, FDA*

Questions:

- What is the most important role of research with respect to the implementation of the FSMA rules?
- What are critical steps for developing a unified, prioritized research agenda?
- What should be the considerations for prioritizing research?
- What are the most important research gaps FDA can help address and how?
- How should the research priorities be communicated to stakeholders?